IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next of Kin of RICHARD SMITH, Deceased,	)	**Case #: 3:05-00444**
	)	**Judge Trauger**
Plaintiff,	)	
-against-	)	
PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY LLC and JOHN DOE(S) 1-10,	)	
Defendants.	)	

PLAINTIFF'S MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE THE TESTIMONY OF DAVID FRANKLIN AND EVIDENCE OF THE *FRANKLIN* LITIGATION

Plaintiff Ruth Smith, by and through her attorneys, respectfully requests that this Court deny in its entirety Defendants' motion *in limine* to exclude testimony of David Franklin and evidence of the *Franklin* litigation on the grounds that: (1) pursuant to Fed. R. Evid. 401, such information is relevant to various salient issues in this litigation, including Defendants' negligence, failure-to-warn, and suppression, and recklessness in not demonstrating the safety of Neurontin in off-label populations to whom the company had notice were using Neurontin; (2) these materials demonstrate Defendants' negligence in knowingly and recklessly promoting Neurontin to off-label populations without performing the adequate pharmacovigilance to ascertain whether Neurontin was safe for such uses; (3) these materials demonstrate that the Defendants had full knowledge of the extent of off label use of Neurontin, that Defendants did not know whether the product was safe for use in those off-label populations, and that

Defendants were negligent and reckless in not taking adequate steps to learn of the safety in these populations; and (4) the probative value of the evidence at issue greatly outweighs any potential unfair prejudice to Defendants.

INTRODUCTION

Dr. David Franklin is very familiar with the subject of Defendants' illegal off-label marketing of Neurontin. Judge Patti B. Saris, who oversees the multidistrict litigation, *In re Neurontin Sales and Marketing Practices and Products Liability Litigation,* presided over Dr. Franklin's *qui tam* action, which exposed Defendants' off-label marketing of Neurontin. Judge Saris also found the testimony of Dr. Franklin to be sufficiently credible to enter restraining orders against Defendants in the *Bulger v. Pfizer Inc.* case on July 29, 2009. There can be no doubt that it is because Defendants are aware that Dr. Franklin is a credible witness, that Defendants have moved to preclude him from taking the stand in this action. Dr. Franklin will appear on Plaintiff's witness list and Plaintiff intends to call him to testify at the upcoming trial.

Defendants admit that David Franklin's testimony relates to the marketing of Neurontin. Docket No. 122. On June 9, 2009, in the multidistrict litigation, *In re Neurontin,* D. Mass. No. 1:04-cv-10981-PBS, Judge Saris issued an Electronic Order relating to a similar motion interposed by Defendants to, *inter alia*, exclude national marketing documents from evidence, and stated the following: "[t]he request to remove evidence related to national marketing is denied." On June 22, 2009, Defendants again moved to exclude evidence of marketing or advertising, and the testimony of David Franklin and evidence of the *Franklin* litigation, basically on essentially the same ground, in *Bulger v. Pfizer Inc.,* see D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1912, which motion Judge Saris denied by Electronic Order on July 24, 2009.

ARGUMENT

"Relevant evidence" means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Moore's Fed. Rules Pamphlet 2009, Fed. R. Evid. 401. Defendants' national marketing documents relating to off-label marketing are admissible at trial to the extent they are relevant to Plaintiff's negligence, failure-to-warn, and negligent pharmacovigilance claims against Defendants. *See In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 618 F. Supp. 2d 96, 114 (D. Mass. 2009)

.In response to Defendants' assertions that Dr. Franklin's testimony is inadmissible because it relates to the marketing of Neurontin (Docket No. 121), Plaintiff refers this Court to the arguments asserted in her opposition to Defendants' motion in *limine* to exclude marketing evidence as if fully incorporated herein. Plaintiff reiterates two salient points regarding that briefing, first, that Judge Saris, in her May 26, 2009 Order, succinctly described the heightened duty to warn that a pharmaceutical manufacturer bears when it engages in off-label marketing of a drug:

> Based on the reasoning of this caselaw, the Court concludes that a manufacturer of a pharmaceutical has a duty to disclose to physicians and patients material facts about the risks of the drug, particularly when it is engaged in off-label marketing for uses not approved by the FDA, if it knows that the plaintiff and/or his prescriber does not know or cannot reasonably discover the undisclosed facts.

Id. at 110 (emphasis added).

Second, the manufacturer's knowledge of off-label use with its drug is inextricably intertwined with a manufacturer's duty to disclose material facts about risks with the drug. While off-label prescribing by physicians is not itself improper, a manufacturer with knowledge of both extensive off-label use and material facts about risks inherent with taking the drug (e.g.,

depression and suicide), has a duty to take action. The testimony of Dr. Franklin and the documents from the *Franklin* litigation demonstrate that Defendants were on notice both of the risks of depression, adverse mood and behavior changes and the increased risk for suicide and of the substantial off-label use of Neurontin and failed to take the appropriate actions to warn individuals like Plaintiff's decedent Richard Smith and his prescribing physicians of these risks. Dr. Franklin's testimony and evidence from the *Franklin* litigation regarding Defendants' national campaign to market Neurontin off-label for unapproved uses are probative of Defendants' negligence and evidence of Defendants' state of mind and that their off-label promotion and fraudulent concealment of the risks from ingestion of Neurontin was intentional. Moreover, Dr. Franklin's testimony and evidence from the *Franklin* litigation show Defendants were malicious, willful, wanton or reckless when they knowingly disregarded the safety of Richard Smith, an off-label user, to risks, about which Defendants were aware but did not warn.

POINT I

EVIDENCE FROM THE FRANKLIN LITIGATION IS RELEVANT TO DEFENDANTS' DUTY OF CARE AND SERVE TO PROVIDE NOTICE THAT DEFENDANTS WERE WELL AWARE THAT NEURONTIN WAS BEING UTILIZED FOR OFF-LABEL POPULATIONS

To be admissible, evidence must be relevant. Fed. R. Evid. 401. Relevant evidence is defined as evidence which may tend to prove or disprove a material fact that is of consequence to the determination of the action.. Fed. R. Evid. 401. Further, the Federal Rules of Evidence provide that "relevant evidence may be excluded if its probative value is substantially outweighed by the risk of (a) undue prejudice, confusion of issues, or misleading the jury or (b) undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403 (emphasis added). The Sixth Circuit has stated that when weighing the prejudicial potential against the probative value of the evidence: "we must view the evidence in the light most

favorable to its proponent giving the evidence its maximum probative force and its minimum reasonable prejudicial value. *Id.; see also Robinson v. Runyon,* 149 F.3d 507, 512 (6th Cir. 1998); *Sutkiewicz v. Monroe County Sheriff,* 110 F.3d 352, 360 (6th Cir. 1997); *Laney v. Celotex Corp.,* 901 F.2d 1319, 1320-21 (6th Cir. 1990); *United States v. Schrock*, 855 F.2d 327, 333 (6th Cir. 1988). Further, when a court under takes such a weighing of the evidence:

> Neither the appellate nor the district court is permitted to consider the weight or sufficiency of the evidence in determining relevancy and "even if a district court believes the evidence is insufficient to prove the ultimate point for which it is offered, it may not exclude the evidence if it has even the slightest probative worth." *Douglass v. Eaton Corp*., 956 F.2d 1339, 1344 (6th Cir. 1992).

Id. at 512.

It is clear that "all relevant evidence is to some degree prejudicial. What the rule discourages is unfair prejudice, which is evidence that has 'an undue tendency to suggest decision on an improper basis, commonly but not necessarily an emotional one.'" *Donathan v. Orthopaedic & Sports Medicine Clinic, PPLC,* No. 4:07-cv-18, 2009 U.S. Dist. LEXIS 99557 at *7 (E.D. Tenn. Oct. 26, 2009) (citing to *United States v. Whittington,* 455 F.3d 736, 739 (6th Cir. 2006). In its determination as to whether evidence should be excluded under Rule 403, "the court should 'give the evidence its maximum reasonable probative force and its minimum reasonable prejudicial value'". *Id.* (citations omitted).

Defendants argue that because Dr. Franklin was only employed by Parke-Davis for four months in 1996 as a medical liaison in a geographic area other than where decedent resided, his testimony could not be relevant to Richard Smith's being harmed by unlawful practices that were witnessed by Dr. Franklin. Defendants would like it to appear that the illegal conduct uncovered in the *Franklin* litigation was merely the unauthorized aberrant conduct of a few individuals. The stark reality is that Defendants paid a $430 million criminal fine and pled to a criminal

offense and the company was penalized because Dr. Franklin blew the whistle on a national campaign of illegal marketing and promotion of Neurontin off-label for unapproved uses. To the extent that Dr. Franklin has knowledge of a national campaign, and that Richard Smith is a victim of that same illegal national marketing campaign, Dr. Franklin's testimony is admissible on several grounds including to prove negligence.

Similar to the national marketing documents, Dr. Franklin's testimony and evidence from the *Franklin* litigation will be utilized by Plaintiff to demonstrate that Defendants breached their duty of care and that Defendants had notice of the deleterious effects posed, depression/suicidality, by ingestion of their drug Neurontin. As detailed in Plaintiff's opposition to Defendants' motion *in limine* to exclude the marketing documents, the manufacturer's knowledge of off-label use with its drug is inextricably intertwined with a manufacturer's duty to disclose material facts about risks with the drug. Defendants were on notice both of the risks of depression and of the substantial off-label use of Neurontin. Dr. Franklin's testimony and evidence from the *Franklin* litigation are probative of Defendants' negligence.

Dr. Franklin's testimony will show the extent of Defendants' knowledge and state of mind in regard to their off-label promotion of Neurontin for unapproved uses. Dr. Franklin was trained by Parke-Davis to engage in the illegal promotion of Neurontin for unapproved uses at training courses that Parke-Davis medical representatives and sales representatives were required to attend. Docket No. 123-3. Dr. Franklin received his training as a Medical Liaison at a Parke-Davis facility in Ann Arbor, Michigan. *Id.* at p. 8 On April 16, 1996, Dr. Franklin attended a Parke-Davis national training seminar in Ann Arbor which was being recorded by videotape. *Id.* After Parke-Davis supervisors and an attorney laid out the FDA rules regarding, *inter alia,* the prohibition of off-label promotion, the supervisors intentionally turned off the video camera and

proceeded to advise how medical liaisons could avoid the FDA rules. *Id.* at pp. 8, 9. During the un-taped session, attendees were instructed that they were expected to convince physicians to prescribe Defendants' pharmaceuticals for their patients: "[W]e expect you to do your job out there and stay focused on sales, don't worry about this stuff just use common sense," and in particular, medical liaisons were instructed that "above all, don't put anything in writing." *Id.*

During formal national liaison training, Dr. Franklin also was taught how to avoid putting anything on paper that would evidence improper off-label presentations in promotional circumstances. *Id.* at pp. 30-31. In addition to national medical liaison training, Dr. Franklin received training from Parke-Davis in sales techniques from physicians. *Id.* at p. 17. He was instructed by Parke-Davis that "'good' results should be highly touted but that 'bad' results should be hidden from view," and he was provided with publications with good results in small samplings of patients to "tout" off-label unapproved uses. *Id.* at p. 18. Clearly, Dr. Franklin is more than qualified to testify to the fact that Defendants' conduct was indeed knowing and intentional conduct. Moreover, the training that Dr. Franklin received was formal national liaison training, not training that was relegated to one geographic area in the United States.

On this issue, Plaintiff is not utilizing Dr. Franklin's testimony or the *Franklin* litigation documents to demonstrate fraud, but is using this evidence to demonstrate Defendants' intentional breach of their common law and statutory duty of care to Richard Smith. Dr. Franklin's testimony is probative as to Plaintiff's claims that Defendants were aware that Neurontin was being promoted and used by physicians for off-label unapproved uses, but that they failed to monitor or provide adequate pharmacovigilance for the unapproved uses and failed in their duty to warn of the risks of Neurontin to physicians of those patients, like Richard Smith, who ingested the drug for pain, an off-label unapproved use.

In *United States v. Barnes,* the Sixth Circuit made it perfectly clear that "intrinsic" acts or evidence do not implicate Fed. R. Evid. 404(b). 49 F.3d 1144, 1149 (6th Cir. 1995). The Court of Appeals defined "intrinsic" acts as "those that are part of a single criminal episode. Rule 404(b) is not implicated when the other crimes or wrongs evidence is part of a continuing pattern of illegal activity." *Id.* The Sixth Circuit affirmed the defendants' convictions for drug trafficking and the trial court's ruling that evidence consisting of testimony that the defendant was expecting to pick up another package of illegal drugs on the date of his arrest while picking up a package of illegal drugs was evidence that "was intrinsically related" to the acts at issue and "that the evidence was admissible under Rule 404(b)." *Id.* at 1145.

The facts are what they are in this case. These are not allegations or prior bad acts from an unrelated prior case or drug litigation. Defendants pled guilty to illegally promoting Neurontin for off-label uses. Defendants intentionally failed to perform the adequate pharmacovigilance even though they were aware of the risks for the off label uses which relegated Neurontin unsafe for off label uses in this litigation. The testimony of David Franklin and the evidence from the *Franklin* litigation that Defendants are attempting to exclude is "intrinsic evidence" to this case concerning Neurontin, not another drug, but the exact drug that is complained about in this case by Plaintiff. Defendants were intentionally illegally promoting this drug off-label for the unapproved use of pain and thus had notice of the drug was being prescribed and ingested off-label, and Defendants had a heightened duty to warn of the risks of ingesting Neurontin. The probative value of this evidence is crucial to Plaintiff's claim and clearly does not pose any unfair prejudice to Defendants.

POINT II

DR. FRANKLIN'S TESTIMONY AND EVIDENCE FROM THE *FRANKLIN* LITIGATION ARE RELEVANT TO DEFENDANTS' FRAUDULENT CONCEALMENT AND SUPPRESSION OF THE RISKS OF ADVERSE MOOD AND BEHAVIOR CHANGES AND INCREASED RISK FOR SUICIDALITY FROM THE INGESTION OF NEURONTIN FROM HARTLEY SHEARER'S PRESCRIBING PHYSICIAN

Judge Saris had previously ruled that Track One Plaintiffs, such as Ruth Smith, in their amended complaints, had sufficiently "allege[d] the elements necessary to establish a claim of fraudulent concealment, "namely that defendants intentionally withheld material information about the side effects of Neurontin from both consumers and their prescribing physicians, with the intent to deceive." *In Re Neurontin,* 618 F. Supp. 2d at 114. Plaintiff alleges that Defendants intentionally and fraudulently concealed or suppressed information concerning the risks of adverse mood and behavior changes and the increased risk for suicidality from the ingestion of Neurontin from Richard Smith's physicians and healthcare providers who prescribed Neurontin to Mr. Smith for pain issues. Defendants actively promoted Neurontin to Mr. Smith's prescribing medical providers via direct sales representative detailing to the doctors' offices. D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1679-14. Nothing in the record reflects that any of Defendants' sales representatives informed Mr. Smith's prescribing medical providers of Neurontin's association with depression/suicidality. Furthermore, whenever a sales representative provided samples or other materials, Neurontin's risk of suicidal and self injurious behavior was not included in the labeling accompanying these materials. But it is known that the providers were detailed, and Mr. Smith was prescribed Neurontin for pain — an off-label, unapproved use. D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1679-13 at 28:14-28:19. In fact, although Defendants acknowledge it was inappropriate to detail physicians other than neurologists and epileptologists (D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1679-15 at 45:8-

45:25; *see* D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1679-16 at 009942), Defendants detailed Mr. Smith's neurosurgeon, an orthopedist, and a nurse. In doing so, Defendants, who breached their own internal standards, fraudulently represented to Mr. Smith's prescribing medical providers that Neurontin was safe and/or efficacious for indications never approved for use by the FDA (i.e., pain and neuropathic pain).

For example, prior to Mr. Smith's death, Defendants' sales representative actively promoted Neurontin to Mr. Smith's orthopedist, Dr. Mackey, and the doctors in his medical practice on approximately 69 occasions with respect to Neurontin. MDL Docket No. 1679-17. Dr. Mackey testified that Defendants detailed him about "neuropathic pain", which is an off-label, unapproved use by the FDA. D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1679-13 at 76:23-77:16.

Defendants' sales representative actively promoted Neurontin to Mr. Smith's healthcare provider, Nurse Pamela Krancer, on approximately 27 occasions with respect to Neurontin. Defendants' sales representative Ashley Pippin planned to "probe" into where Nurse Krancer was dispensing Neurontin and "get help through her with other surgeons." D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1679-18. Defendants' sales representatives clearly acted on this "probe" plan as evidenced by the more than 300 occasions in which Defendants detailed the medical practice and distributed Neurontin samples[1] to the medical practice where both Mr. Smith sought treatment and Nurse Krancer worked. D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1679-19.

Defendants' sales representative also detailed Dr. McCombs, a neurosurgeon, on

[1] Noteworthy, each distribution of a Neurontin sample to the medical practice also included the Neurontin Label which Defendants admit provided inadequate directions for unapproved uses. This admission is reflected in their 2004 guilty plea for distributing a misbranded drug. *See* MDL Docket No. 1200-3, Ex. 2.

approximately three occasions with respect to Neurontin. D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1679-20.

Dr. Mackey acknowledged that his understanding of Neurontin's off-label use to treat Dr. Smith's pain was in part based upon his interactions with other doctors in his practice. D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1679-13 at 27:6-27:13. Dr. Mackey subscribed to journals and he consulted physicians outside of his practice as well as with his two partners — neither of whom were neurologists or epileptologists — but both had been detailed extensively by Defendants about Neurontin for off-label uses. D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1679-17; MDL Docket No. 1679-13 at 28:20-31:25, 74:1-74:23. Dr. Mackey acknowledged that he utilized the Physician's Desk Reference, which would have included the Neurontin label, for his risk/benefit analysis before prescribing a drug. D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1279-13 at 73:12-73:25. Dr. Mackey also testified that he had been detailed by Defendants' sales representative regarding Neurontin, who discussed Neurontin usage and provided samples for distribution. D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1679-13 at 75:7-78:4.

The evidence of Defendants' guilt related to their admitted fraud and off-label promotion scheme, coupled with the documented promotional visits by sales representatives, and testimony from Mr. Smith's prescribing medical providers, demonstrates that prescribers were influenced by Defendants' affirmative fraudulent promotion of Neurontin as safe and effective for treatment of pain, depression or anxiety — all off-label uses. *See In re Pharmaceutical Ind. Avg. Wholesale Price Litig.*, 252 F.R.D. 83, 99 (D. Mass. 2008) (where plaintiffs' damages were alleged to be caused by a lengthy course of prohibited conduct that affected a large number of consumers, the showing of reliance need not include direct evidence of reliance by individual consumers of defendants' products").

Dr. Franklin's testimony and evidence from the *Franklin* litigation regarding Defendants' elaborate and multi-faceted strategy to promote Neurontin through sales representative contact with physicians, sales representative training, etc., is relevant to Plaintiff's claims of fraudulent concealment or suppression of the risks of increased suicide for Neurontin.

Moreover, Plaintiff's decedent's prescribing physician, Dr. Mackey, particularly testified that he was not aware of various important information concerning problems with Neurontin, depression and suicide, and that had he been told of these problems with Neurontin, he "[c]ertainly" would have given Mr. Smith specific warnings and told him to be observant about side effects; and Nurse Krancer testified that had Defendants told her that Neurontin was associated with increases in depression and suicide, she would have educated the patients on these potential side effects. *See* D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1678, Further Statement, ¶¶ 15-23, re Learned Intermediary. Mr. Smith's prescribing medical providers, Dr. Paul McCombs and Dr. Mackey, testified about the material information suppressed by Defendants. Both doctors, in discussing their prescribing practices and risk/benefit analyses for prescribing a drug to Mr. Smith, wanted to know about suicide attempts during clinical trials; depression adverse events during clinical trials, and whether depression and suicidality were side effects. D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1679-12 at 12:3-12:19, 12:20-14:23, 28:10-29:19; MDL Docket No. 1679-13 at 34:14-36:25.

Dr. Franklin disclosed that false information regarding clinical trials was routinely given to physicians, and negative information about the drug's effectiveness for bipolar disorder and pain was suppressed. Docket No. 123-34 at pp. 21-28. In contrasting the requirements for failure to warn claims from fraudulent concealment claims, Judge Saris stated that "claims based on a fraudulent concealment or misrepresentation require scienter." *In Re Neurontin Mktg.,*

Sales Practices & Prods. Liab. Litig., 618 F. Supp. 2d at 113. Judge Saris recognized in the *Bulger* case, by denying essentially an identical motion *in limine*, that this evidence is relevant to, and admissible on, the issue of corporate intent — it provides the requisite evidence of Defendants' scienter in this case. Clearly Dr. Franklin may provide testimony pertaining to the training that sales representative received from Defendants in which they were instructed to fraudulently conceal or suppress the risks of Neurontin from physicians in their off-label promotion of Neurontin for pain.

Moreover, Dr. Franklin and the *Franklin* litigation evidence will demonstrate the way that Defendants utilized an elaborate off-label marketing plan which included a series of tactics including peer-to-peer marketing. As noted *supra*, Dr. Mackey testified that he consulted physicians outside of his practice as well as with his two partners — neither of whom were neurologists or epileptologists — but both had been detailed extensively by Defendants.

Dr. Franklin will be able to provide personal knowledge on the way that each of these programs worked and explain how Defendants designed same to fraudulently conceal or suppress the risks of adverse mood and behavior changes in order to influence physicians, such as Dr. Mackey, who was detailed by sales representatives who suppressed the risks, to induce him to prescribe Neurontin off-label for pain.

Plaintiff has not designated Dr. Franklin as an expert and she does not intend to seek his opinion as an expert opinion under Rule 702. To the extent Plaintiff seeks to elicit any opinion testimony from Dr. Franklin, its admissibility will depend upon a straightforward application of Fed. R. Evid. 701. Dr. Franklin will be testifying live at trial; consequently, Defendants are solely speculating in their motion *in limine* regarding the types of opinion that Dr. Franklin might be permitted to provide. If and when Plaintiff's counsel seeks Dr. Franklin's opinion on the

stand on a questionable issue, the matter will best be addressed by a timely objection before this Court at the time of trial. The Court can then rule based upon a full record and in context. There is no compelling reason to provide Defendants with an advisory opinion on admissible opinions.

Plaintiff, however, disputes Defendants' assertion that Dr. Franklin should be prevented from providing testimony regarding Parke-Davis' compliance with FDA marketing regulation because he is not designated as an expert on the FDA. Individuals who work in a highly regulated industry, such as the pharmaceutical industry, are often allowed to provide testimony concerning their understanding, and that of their company, of the rules that govern their particular industry. A witness, such as Dr. Franklin, does not require a legal degree to testify about specialized rules and/or regulations if the witness is required to deal with same on a daily basis and has personal experience with them. *See, e.g.*, *Bradley v. Philips Chem. Co., Inc.*, 484 F. Supp. 2d 604, 616, n.34 (S.D. Tex. 2007) (risk manager with years of experience issuing workers' compensation policies and complying with state regulations affecting such policies could give lay opinion under Rule 701 regarding the construction of the workers' compensation policy at issue and related state regulations). Therefore, Dr. Franklin can testify concerning both his and Parke-Davis' understanding of the FDA marketing rules and regulatory requirements during the period of his employment with Parke-Davis. Further, Dr. Franklin can testify, based upon his own personal observations or upon admissions made to him by Defendants' officers and employees, whether Parke-Davis complied with its understanding of the FDA regulatory rule regarding marketing.[2] Moreover, Dr. Franklin can testify concerning specific conduct that he personally observed that would allow the jury to make its own determination whether Parke-Davis conducted its marketing of Neurontin in compliance with the applicable FDA rules.

[2] Defendant Warner-Lambert should be precluded from contending that they operated in compliance with the FDA's marketing rules because Defendants pled guilty to felony violations of distributing a drug for uses unapproved by the FDA and for distributing misbranded drugs.

Similarly, Dr. Franklin, based upon personal observation/knowledge or admissions made to him by Defendants' corporate employees, can testify that Parke-Davis encouraged the promotion of Neurontin for off-label use for unapproved indications. Moreover, as detailed *supra,* Dr. Franklin can testify concerning Parke-Davis' scienter, that the company knew its representations concerning the drug's off-label uses were not truthful and that the risks were being fraudulently concealed and/or suppressed.

POINT III

DR. FRANKLIN'S DISCLOSURE, RECORDINGS AND RECOLLECTION OF STATEMENTS EXHORTING PARKE-DAVIS EMPLOYEES TO ENGAGE IN UNLAWFUL MARKETING IS NOT INADMISSIBLE HEARSAY

Defendants allege that David Franklin's disclosure should be excluded in this case. Docket No. 122 at 7. Dr. Franklin's Disclosure (Docket No. 123-3), and the quotations included therein, was compiled to reflect Dr. Franklin's knowledge of the events while they were still fresh in his memory, in the summer of 1996, a mere number of weeks after the events had occurred. A *qui tam* disclosure is intended to be a correct statement of all material facts known by a Relator, Dr. Franklin. Dr. Franklin attached to his Disclosure verbatim transcripts of conversations among Parke-Davis employees that were routinely recorded and preserved on the company's Aspen voice-mail system. Dr. Franklin also produced for the Defendants in the *Franklin* litigation the tape from which the transcripts were made. The recordings (and the resulting transcripts) capture conversations between members of the NECBU discussing how medical liaisons could be used by the sales force to increase Neurontin sales, particularly for unapproved uses. The tapes, however, are comprised exclusively of statements from persons who were employees of Defendants at the time the conversations were recorded. The tapes clearly constitute admissions of a party opponent, and are not considered hearsay pursuant to

Fed. R. Evid. 801 (d)(2). *Cuddy v. Wal-Mart Super Center, Inc.*, 993 F. Supp. 962, 967 (W.D. Va. 1998) (tape recording of conversation with corporate employee constituted admission of a party opponent under Fed. R. Evid. 801(d)(2)(D) and could not be excluded as hearsay).

Defendants point to Plaintiff's designation of a statement by Dr. Franklin in which he quotes a statement made by Mr. Ford, a Sales Director of the Northeast Customer Business Unit instructing other Defendant employees to utilize various marketing techniques to promote Neurontin. Defs.' Mem., Docket No. 122 at 7, 8. Pursuant to Fed. R. Evid. 801.5, Plaintiff will use the statement not to prove the truth of the matter asserted as suggested by Defendants, but for the fact that Defendants had notice or knowledge that the drug was to be used off-label, and thus combined with their knowledge of the inherent risks of taking the drug, Defendants had a duty to perform adequate pharmacovigilance. *See United States v. Emmons,* 24 F.3d 1210, 1216-17 (10th Cir. 1994) (map found in defendant's home demonstrated that he had knowledge of where marijuana plants were situated on property he owned).

Moreover, the statement in question by Defendants' agent Mr. Ford, that "I don't want to hear that safety crap either, have you tried Neurontin, every one of you should take one just to see there is nothing, its just a great drug," is sought to be admitted not for the truth of the matter asserted, but to demonstrate that Defendants had notice that Neurontin was not safe for off-label uses. *See Worsham v. A.H. Robins Co.,* 734 F.2d 676, 687 (11th Cir. 1984) (complaint letters were admissible because not to demonstrate that product had caused the injury but that defendants had notice that product was potentially dangerous). Furthermore, as this statement was made by Mr. Ford, a Parke-Davis employee, it clearly constitutes an admission of a party opponent, and is not considered hearsay pursuant to Fed. R. Evid. 801 (d)(2).

That Defendants alleged that Mr. Franklin later made a contrary statement does not go to the admissibility of the statement but rather goes to the weight of the evidence to be attached by a finder of fact. Further, the statement is a prior inconsistent statement under Fed. R. Evid. 801.6[3], because Defendants have claimed in this litigation to be unaware that there were any safety concerns regarding Neurontin, whereas the statement by their agent, Mr. Ford, clearly demonstrates that some within the corporation were aware of "safety crap" and had concerns.

Defendants, however, assert that Dr. Franklin may only testify about the Ford statement (and any other statements in the Disclosure) based on his current memory at the time he is called to the stand. That is not necessarily true. Dr. Franklin's memorialization of the statement in his Disclosure likely qualifies as a recorded recollection under Rule 803(5). If Dr. Franklin is unable to recall the matter sufficiently and fully, Plaintiff may read the statement into the record if Dr. Franklin establishes that he recorded the Ford Statement in the Disclosure when the matter was fresh in his mind and it was made to correctly reflect his knowledge.

As noted *supra*, the Disclosure was compiled in the summer of 1996, only weeks after the actual events occurred. The Court, of course, cannot make a definitive determination if memorialization of the Ford Statement and the other quotations referenced in the Disclosure qualify for the recorded recollection exception to the hearsay rule until the witness has testified and the Court can determine that Plaintiff has provided the necessary factual predicate for admission. Consequently, the Court cannot issue a blanket order at this time that the Ford Statement cannot be read to the jury. Plaintiff respectfully requests that this Court defer decision until it can determine whether Rule 803(5) is applicable.

Nor can Defendants prohibit Plaintiff's counsel from attempting to refresh Dr. Franklin's recollection, if necessary, by reviewing the document. Counsel realizes there are limitations on

how a witness's memory can be refreshed, but there is no basis to believe that Plaintiff's counsel will not comply with the proper procedures for refreshing memory or that the Court will be unable to monitor the situation if the witness cannot clearly recall the statements. Again, there is no reason for the Court to make an *in limine* ruling when the matter can be easily and completely addressed at the time the issue arises in the course of a trial.

Defendants allege that the *Franklin* depositions are not admissible as former testimony under Fed. R. Evid. 804(b)(1) because the only question in the *qui tam* action was whether Warner-Lambert promoted Neurontin off-label and whether such off-label promotion caused the submission to Medicaid of Neurontin prescriptions that were ineligible for reimbursement. — that Defendants' "motive in cross examining the *Franklin* witnesses was merely to demonstrate that it did not encourage off-label promotion of Neurontin." Docket No. 122, at 9,10. Defendants are just plain wrong when they state that "that question is wholly irrelevant to the instant case." *Id.* As detailed throughout this brief in opposition, Plaintiff requires the evidence in question to demonstrate that Defendants were not only aware of the off-label promotion but that Defendants encouraged the off-label promotion — Defendants' intent and state of mind — precisely the same issues that Defendants encountered in the *qui tam* action.

Plaintiff requires the documents and testimony, etc., from the *Franklin* litigation to demonstrate Defendants' negligence, breach of duty and their intentional and reckless disregard for the health and safety of Neurontin off-label users because Defendants made a conscious decision to engage in and encourage the off-label promotion rather than to perform the required pharmacovigilance for the off-label uses. These documents and testimony will show that Defendants were well aware that there were safety concerns for the use of Neurontin to the off-label population and will provide evidence of Defendants' reckless indifference in their breach of

their duty of care for which the probative value substantially outweighs any potential for unfair prejudice to Defendants.

POINT IV

DEFENDANTS' BREACH OF THEIR DUTY OF CARE AND THEIR RECKLESS INDIFFERENCE TO THE SAFETY OF OFF-LABEL USERS OF NEURONTIN AS DEMONSTRATED BY DR. FRANKLIN'S TESTIMONY AND THE *FRANKLIN* LITIGATION, ARE PROPER EVIDENCE FOR THE ISSUE OF PUNITIVE DAMAGES

In this case, Dr. Franklin's testimony, evidence from the *Franklin* litigation all emanate from the same breach of Defendants' duty of care and will be utilized for an appropriate purpose to demonstrate notice. Moreover, as noted in detail above, what is perfectly clear is that Defendants were negligent and reckless in knowingly not performing adequate pharmacovigilance to ascertain whether the drug was safe for the off-label uses by the population for which Defendants were promoting the drug off-label, and Defendants' breach will be demonstrated by the testimony of Dr. Franklin and evidence from the *Franklin* litigation, which Plaintiff will show harmed and caused the death of Richard Smith.

The Supreme Court of Tennessee, in *Flax v. DaimlerChrysler Corp.,* stated in regard to the standard for punitive damages:

> A verdict imposing punitive damages must be supported by clear and convincing evidence that the defendant acted intentionally, fraudulently, maliciously, or recklessly. *Hodges c. S.C. Roff & Co.,* 833 S.W.2d 896, 901 (Tenn. 1992). In *Hodges*, we held that evidence is clear and convincing when it leaves "no serious or substantial doubt about the correctness of the conclusions drawn." *Id.* at 901 n.3. We also held that a person acts recklessly when "the person is aware of, but consciously disregards, a substantial and unjustifiable risk of such a nature that its disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances." *Id.* at 901. The jury in this case found that there was clear and convincing evidence that DCC's conduct was reckless.

272 S.W.3d 521, 531 (Tenn. 2008).

Plaintiff requires Dr. Franklin's testimony and the evidence from the *Franklin* litigation to demonstrate that Defendants were malicious, willful, intentional, wanton or reckless when they knowingly disregarded the safety of Richard Smith, an off-label user, to risks**, about which Defendants were aware but did not warn,** and thereby intentionally breached their duty of care in promoting Neurontin for such an off-label use rather than performing pharmacovigilance. Defendants' intentional and reckless conduct is intertwined and directly related, and not independent, with their breach of their duty of care for which Plaintiff claims that Defendants are liable for the injuries and death sustained by Richard Smith in this case. Plaintiff intends to have Dr. Franklin testify and utilize evidence from the *Franklin* litigation as evidence to demonstrate that Defendants had knowledge of the risks of increased suicidality and that, instead of performing the pharmacovigilance required, intentionally breached their duty of care by sitting on their hands and not warning Richard Smith and his prescribers of such risks. This is the conduct that is reprehensible and for which punitive damages should be considered.

CONCLUSION

Plaintiff respectfully requests that this Court deny Defendants' motion *in limine* to exclude the testimony of Dr. David Franklin and evidence from the *Franklin* litigation, and find that these materials are relevant to Defendants' knowledge of the risks of Neurontin, duty of care, negligent and reckless disregard and punitive damages and that their probative value greatly outweighs any alleged prejudice to Defendants.

Dated: April 27, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 27th day of April, 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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